

Benjamin E. Chu, M.D., M.P.H., M.A.C.P., Chair
President, Southern California Region
Kaiser Foundation Health Plan and Hospitals
Pasadena, CA

Susan Curry, Ph.D., Vice-Chair
Dean, College of Public Health
Distinguished Professor, Health Management and Policy
University of Iowa
Iowa City, IA

Lawrence G. Wasden, Treasurer
Attorney General of Idaho
Boise, ID

Donald K. Boswell
President & CEO
Western New York Public Broadcasting Association
Buffalo, NY

Jonathan E. Fielding, M.D., M.P.H.
Director Health Officer, Los Angeles County Department
of Public Health
Professor of Health Services and Pediatrics,
Schools of Public Health and Medicine,
University of California, Los Angeles
Los Angeles, CA

Tom Miller
Attorney General of Iowa
Des Moines, IA

Charles K. Scott
Wyoming State Senator
Casper, WY

Leticia Van de Putte
Texas State Senator
San Antonio, TX

Cass Wheeler
Chief Executive Officer Emeritus
American Heart Association
Dallas, TX

Bethlehem Berni (Youth Board Liaison)
Temple University
Philadelphia, PA

Cheryl G. Heaton, Dr. P.H., Ex-Officio
President & CEO
American Legacy Foundation

Legacy is pleased to submit comments in support of the *Draft Guidance for Industry: Listing of Ingredients in Tobacco Products* (Draft Guidance) released by the Food and Drug Administration (FDA) on October 30, 2009.

Legacy is dedicated to building a world where young people reject tobacco and anyone can quit. Located in Washington, D.C., Legacy develops programs that address the health effects of tobacco use, including **truth**®, an award-winning youth smoking prevention campaign, and **EX**®, an innovative tobacco cessation program. Legacy also conducts research exploring the causes, consequences and approaches to reducing tobacco use and operates a nationally-renowned program of outreach to priority populations who disproportionately bear the toll of tobacco. Legacy was created as a result of the 1998 Master Settlement Agreement (MSA) between the states and the tobacco industry. Pursuant to the terms of the MSA, Legacy cannot lobby, and therefore took no position on FSPTCA as it made its way through the legislative process.

Section 904 of the Federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act) requires tobacco manufacturers to submit a list of ingredients included in their tobacco products, as well as all documents dated after passage of the Tobacco Control Act (June 22, 2009) that relate to the health effects of these products. The current Draft Guidance only provides guidance regarding the ingredient listing, and does not address the Tobacco Control Act's requirement that tobacco manufacturers submit all documents related to health effects.

Information regarding ingredients in tobacco products is of vital importance to the FDA as it implements its new regulatory responsibility over these products. Such information will help educate the American people about what ingredients comprise the tobacco products they use, and can be useful to public health officials in developing more effective campaigns and programs to prevent tobacco use and help tobacco users quit. As such, as the Tobacco Control Act prescribes, this information must be disclosed to the FDA and also belongs squarely in the public domain.

Prior to passage of the Tobacco Control Act, the only information tobacco companies were required to disclose about the ingredients in their products is a composite list of cigarette ingredients submitted annually to the Secretary of Health and Human Services pursuant to

the Federal Cigarette Labeling and Advertising Act of 1966, 15 U.S.C. §§ 1331-1340. Given that this information is required by statute *not* to “identify the company which uses the ingredients or the brand of cigarettes which contain the ingredients,” 15 U.S.C. § 1335a (a), and is only made publicly available if the Secretary determines it appropriate to include in a report to Congress, *see id.* at § 1335a(b)(1)-(2), it is of limited utility to the scientific and public health community’s efforts to fully understand the health effects of tobacco. Importantly, it is also of no utility to consumers who seek information about ingredients in specific tobacco brands and sub brands.

Accordingly, the Tobacco Control Act’s requirement that the industry disclose all ingredients by brand and by quantity in each brand and sub brand will have great practical utility. It will not only provide important and reliable information to the consumer, but it could also advance our understanding of how specific cigarette ingredients contribute to the adverse health effects of tobacco use. Such information will consequently aid in the development of more targeted and effective prevention and treatment programs.

Legacy reiterates its previously stated position that FDA should narrowly construe confidentiality provisions and urges the FDA to act forcefully, to the full extent permitted by law, to ensure public access to information submitted to it by the tobacco industry. One of the most important achievements of the Master Settlement Agreement was to require the public disclosure of decades of internal tobacco industry documents. Legacy in fact provided a \$10 million endowment to the University of California to facilitate the permanent availability of, and access to, these documents. These documents, which are still being mined by researchers, played a critical role in exposing the deadly, decades long fraud perpetrated by the industry on the American public outlined in great detail in *United States v. Philip Morris, et al.*, 449 F. Supp. 2d 1 (D.D.C. 2006) *aff’d*, 566 F.3d 1095 (D.C.Cir.2009).

These documents furnish the support for many of Congress’ key findings in the Tobacco Control Act. But the industry’s document disclosure obligations under the MSA will soon come to an end. The documents required to be submitted by the industry to the FDA under the Tobacco Control Act will thus assume significant importance. The industry must not be allowed to hide behind overbroad assertions of trade secrets and other claims to bar public access to information that legitimately and importantly belongs in the public domain – preferably on a publicly accessible website in order to best disseminate the information. We hope that the statement in the draft guidance referring to the confidentiality of this information (Section F of the Draft Guidance) is not a signal that this information will not be available to the public and to public health officials.

We applaud the FDA for quickly developing this helpful draft guidance. We look forward to the final version and to using the important information that will inevitably be garnered as a result.